K042211

NOV - 8 2004

510(k) SUMMARY

PhotoMedex, Inc.
LaserPro 810, 940 and 980 Systems Diode Laser Systems

1. GENERAL

- *Submitter:* PhotoMedex, Inc.
  147 Keystone Drive
  Montgomeryville, PA, 18936

- *Contact Person:* Bob Rose
- *Date Prepared:* August 13, 2004 (Revised September 15, 2004)

2. DEVICE NAME

- *Classification name:* Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)

- *Common or usual name:* Diode laser

- *Trade or proprietary name:* LaserPro Diode Surgical Laser System

3. PREDICATE DEVICE (Device to be Modified)

Diode Surgical Laser Systems

- **PhotoMedex LaserPro 810, 940 and 980 Diode Laser Systems (K040294)**

4. DEVICE DESCRIPTION and DEVICE MODIFICATIONS

The PhotoMedex LaserPro 810, 940 and 980 Diode Laser Systems are designed to provide laser power at wavelengths of 810nm, 940nm, and 980nm, depending on model, which can be used for the procedures indicated in the next section of this summary. These devices have been cleared previously via K040294. Differences between the cleared and modified device are limited to:

- Maximum output power increased from 20 to 25 Watts (Systems are identified by output frequency and maximum power).
- User adjustable (intensity) aiming beam (the maximum aiming beam optical power ***does not change*** from currently cleared device).

The system is comprised of the following main components:

- A laser console/cabinet with fiber port to accept SMA-905 connectors.
- Display panel with soft-touch keypad control and separate Emergency Off button.
- Laser system microprocessor control electronics with operating software
- A detachable covered footswitch.

5. INDICATIONS FOR USE

The PhotoMedex LaserPro 810. 940 and 980 Diode Laser Systems (and the fiber delivery systems and accessories that are used with them to deliver laser energy) are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including:

Gastroenterology

The ablation, vaporization, excision, incision, and coagulation of soft tissue in gastroenterology procedures. Applications include: hemostasis of esophageal varices, palliation of malignant dysphagia, palliative ablation of obstructive neoplasms, hemostasis of colonoscopy.

Neurosurgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in neurosurgery procedures. Applications include: tumors adjacent to the spinal cord, tumors adjacent to the cortex.

General Surgery

Treatment of varicose veins and varicosities associated with superficial reflux of the greater saphenous vein. The ablation, vaporization, excision, incision, and coagulation of soft tissue in general surgery including endoscopic and open procedures. Applications include: Laparoscopic appendectomy, cholecystectomy, and bowel resection. Open: mastectomy, reduction mammoplasty, breast biopsy, rectal and anal hemorrhoidectomy, bowel resection, colectomy, cholecystectomy, liver resection, condyloma, thyroidectomy, thoracotomy, and cavernous hemangioma.

Genitourinary (Urology)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in genitourinary (urology) procedures. Applications include: Transurethral incision of the prostate (TUIP), bladder tumors, bladder neck incisions, urethral strictures, and exterior sphincterotomy. Laparoscopic lymphadenectomy. Open; condyloma, circumcision, and benign and malignant lesions of external genitalia.

Thoracic Surgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in thoracic surgery including endoscopic and open procedures. Applications include: pulmonary resection, coagulation of blebs and bullae, adhesiolysis, pericardiectomy, mediastinal and thoracic lesions and abnormalities, mediastinal lymph node dissection, and hemostasis, thoracotomy.

Gynecology (GYN)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in gynecology (GYN) procedures. Applications include: Laparoscopic, excision/lysis of adhesions, endometrial lesions, including ablation of endometriosis, laparoscopic assisted hysterectomy (LAVH), laser uterosacral nerve ablation (LUNA), myomectomy, ovarian cystectomy, ovarian drilling, tubal fimbrioplasty, and appendectomy. Open: conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia VIN, VAIN. Condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions. Intrauterine; fibroids/polyps/adhesions, resection of septum.

Pulmonology

The ablation, vaporization, excision, incision, and coagulation of soft tissue in pulmonology procedures. Applications include: tracheal bronchial lesions.

Opthomology

The ablation, vaporization, excision, incision, and coagulation of soft tissue in ophthalmology procedures. Applications include: Oculoplastics, open DCR, endo-nasal DCR, tumor excision (and) biopsy, eyelid reconstruction, and blepharoplasty.

Orthopedics

The ablation, vaporization, excision, incision, and coagulation of soft tissue in orthopedic surgery procedures. Applications include: dissect and coagulate.

Otolaryngology (ENT)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in otolaryngology procedures. Applications include: Nasal/Sinus; turbinectomy and turbinate reduction/ablation, polypectomy of nose and nasal passages, ethmoidectomy, and meatal antrostomy. Laryngo-tracheal; removal of vocal cord/fold nodules, polyps and cysts, arytenoidectomy, and tracheal stenosis. Oropharyngeal; uvulopalatoplasty (LAUP, laser UPPP), tonsillectomy (including tonsillar cryptolysis, neoplasma) tonsil, and hemi glossectomy. Head & Neck; tumor resection on oral, subfacial and neck tissues, parathyroidectomy, and thyroidectomy.

6. SUBSTANTIAL EQUIVALENCE

The PhotoMedex LaserPro 810, 940 and 980 Diode Laser Systems, when used in conjunction with cleared delivery accessories, share the same indications for use, similar design features, functional features, and therefore are substantially equivalent to the predicate devices which includes the Diomed D15 & D30 Laser Systems (K023543), the Premier Aurora Laser System (K954316), and the SLT Thermalite 810, 940 & 980 Laser Systems (K952661).

7. SAFETY AND EFECTIVENESS

The PhotoMedex LaserPro 810. 940 and 980 Diode Laser Systems are designed, tested and manufactured in accordance with both mandatory and voluntary Standards ensuring when used with marketed cleared delivery systems identified to be compatible, they are considered both safe and effective for the medical applications indicated. No new clinical indications are to be provided by the introduction of LaserPro Diode Surgical Lasers as compared to the identified predicates, which have previously demonstrated clinical effectiveness.

8. CONCLUSIONS

PhotoMedex believes that the (minor) modifications to the LaserPro 810. 940 and 980 Diode Laser Systems are substantially equivalent to, and are safe and effective as the legally marketed identified predicate devices, the LaserPro 810, 940 and 980 Diode Laser Systems (K040294), in that they share identical mechanisms for laser energy delivery and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 2004

Mr. Robert Rose
Director of Regulatory Affairs and Quality Assurance
PhotoMedex, Inc.,
147 Keystone Drive
Montgomeryville, Pennsylvania 18936

Re: K042211
Trade/Device Name: LaserPro 810, 940 and 980 Surgical Diode Laser Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: August 13, 2004
Received: August 16, 2004

Dear Mr. Rose:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if Known): K042211

Device Name: LaserPro 810, 940 and 980 Surgical Diode Laser Systems

Indications For Use:

The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems, (and the fiber delivery systems and accessories used to deliver laser energy), are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), orthopedics, ophthalmology, pulmonology, and thoracic surgery.

The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems are indicated for use in the performance of specific surgical applications in gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), orthopedics, ophthalmology, pulmonology, and thoracic surgery as follows:

Gastroenterology

The ablation, vaporization, excision, incision, and coagulation of soft tissue in gastroenterology procedures. Applications include:

- hemostasis of esophageal varices;
- palliation of malignant dysphagia;
- palliative ablation of obstructive neoplasms;
- hemostasis of colonoscopy.

***** Page 1 of 6 (Indications For Use Continued on Next Page; 6 pages total) *****

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use _____
(Per 21 CFR 801.109)

Indications for Use Statement

510(k) Number (if Known): K042211

Device Name: LaserPro 810, 940 and 980 Surgical Diode Laser Systems

Indications For Use:

Continued from previous page:

Neurosurgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in neurosurgery procedures. Applications include:

- tumors adjacent to the spinal cord;
- tumors adjacent to the cortex.

General Surgery

Treatment of varicose veins and varicosities associated with superficial reflux of the greater saphenous vein.

The ablation, vaporization, excision, incision, and coagulation of soft tissue in general surgery including endoscopic and open procedures. Applications include:

- Laparoscopic
  - appendectomy;
  - cholecystectomy;
  - bowel resection.

- Open
  - mastectomy;
  - reduction mammoplasty;
  - breast biopsy;
  - rectal and anal hemorrhoidectomy;
  - bowel resection;
  - colectomy;
  - cholecystectomy;
  - liver resection;
  - condyloma;
  - thyroidectomy;
  - thoracotomy;
  - cavernous hemangioma.

Indications for Use Statement

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Device Name: LaserPro 810, 940 and 980 Surgical Diode Laser Systems

Indications For Use:

Continued from previous page:

Genitourinary (Urology)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in genitourinary (urology) procedures. Applications include:

- Transurethral
  - transurethral incision of the prostate (TUIP);
  - bladder tumors;
  - bladder neck incisions;
  - urethral strictures;
  - exterior sphincterotomy.

- Laparoscopic
  - Lymphadenectomy.

- Open
  - condyloma;
  - circumcision
  - benign and malignant lesions of external genitalia.

Thoracic Surgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in thoracic surgery including endoscopic and open procedures. Applications include:

- pulmonary resection;
- coagulation of blebs and bullae;
- adhesiolysis;
- pericardiectomy
- mediastinal and thoracic lesions and abnormalities;
- mediastinal lymph node dissection;
- hemostasis;
- thoracotomy.

Indications for Use Statement

510(k) Number (if Known): K042211

Device Name: LaserPro 810, 940 and 980 Surgical Diode Laser Systems

Indications For Use:

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Gynecology (GYN)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in gynecology (GYN) procedures. Applications include:

- Laparoscopic
  - excision/lysis of adhesions;
  - endometrial lesions, including ablation of endometriosis;
  - laparoscopic assisted hysterectomy (LAVH);
  - laser uterosacral nerve ablation (LUNA);
  - myomectomy;
  - ovarian cystectomy;
  - ovarian drilling;
  - tubal fimbrioplasty;
  - appendectomy.

- Open
  - conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia VIN, VAIN;
  - condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions.

- Intrauterine
  - Fibroids/polyps/adhesions;
  - Resection of septum.

Pulmonology

The ablation, vaporization, excision, incision, and coagulation of soft tissue in pulmonology procedures. Applications include:

- tracheal bronchial lesions.

Indications for Use Statement

510(k) Number (if Known): K042211

Device Name: LaserPro 810, 940 and 980 Surgical Diode Laser Systems

Indications For Use:

Continued from previous page:

Opthomology

The ablation, vaporization, excision, incision, and coagulation of soft tissue in ophthalmology procedures. Applications include:

- Oculoplastics
  - open DCR;
  - endo-nasal DCR;
  - tumor excision and biopsy;
  - eyelid reconstruction;
  - blepharoplasty.

Orthopedics

The ablation, vaporization, excision, incision, and coagulation of soft tissue in orthopedic surgery procedures. Applications include:

- Open
  - Dissect and coagulate.

Indications for Use Statement

510(k) Number (if Known): K042211

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Indications For Use:

Continued from previous page:

Otolaryngology (ENT)

The ablation, vaporization, excision, incision, and coagulation of soft tissue in otolaryngology procedures. Applications include:

- Nasal/Sinus
  - turbinectomy and turbinate reduction/ablation;
  - polypectomy of nose and nasal passages;
  - ethmoidectomy;
  - meatal antrostomy;

- Laryngo-tracheal
  - removal of vocal cord/fold nodules, polyps and cysts;
  - arytenoidectomy;
  - tracheal stenosis;

- Oropharyngeal
  - uvulopalatoplasty (LAUP, laser UPPP);
  - tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil;
  - hemi glossectomy;

- Head & Neck
  - tumor resection on oral, subfacial and neck tissues;
  - parathyroidectomy;
  - thyroidectomy.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K042211